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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/299,139	04/23/99	BROWNING J	A013

HM22/0328

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EXAMINER	
VANDER VEGT,F	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/299,139	Applicant(s) Browning et al
	Examiner F. Pierre VanderVegt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Aug 15, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-50* is/~~are~~ pending in the application.

Of the above, claim(s) *17, 18, and 36-50* is/~~are~~ withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 3, 4, 9, 13, 15, 16, 19, 21, 22, 26, 28, 29, 34, and 35* is/~~are~~ rejected.

☒ Claim(s) *2, 5-8, 10-12, 14, 20, 23-25, 27, and 30-33* is/~~are~~ objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a continuation of PCT serial number PCT/US97/19436, which claims priority to provisional application 60/029,060.

Claims 1-50 are currently pending in this application.

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-16 and 19-35, and species (b), soluble LTBR, in Paper No. 4, filed August 15, 2000, is acknowledged.

Upon further review, the species requirement has been removed and all claims in group I are being examined in this Office Action.

2. Applicant's election of the invention of Group I in Paper No. 4 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement between the inventions defining the different groups, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. **Claims 17, 18 and 36-50 are withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Accordingly, **claims 1-16 and 19-35 are the subject of examination** in this Office Action.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). The addresses of inventors Rennert and Mackay have been changed without being initialed.

It does not identify the post office address of each inventor. A post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The post office address should include the ZIP Code designation.

Specification

5. The disclosure is objected to because of the following informalities:

Page 33, lines 19-20, discloses the address of the international depository American Type Culture Collection (A.T.C.C.) as Rockville, Maryland. The Examiner wishes to note that the depository has relocated since the filing of the instant application. The specification should be amended to reflect the full current address of ATCC by replacing the said address with --10801 University Boulevard, Manassas, VA 20110-2209--. Applicant should further disclose the full name of the depository upon its first appearance in the specification.

Claim Rejections - 35 USC § 112

6. Claims 1, 3, 4, 15, 16, 19, 21, 22, 28, 29 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to the use of an "LT-β-R blocking agent" to treat a subject. The instant specification discloses soluble LT-β-R, anti-LT-β-R antibody and anti-LT ligand antibody as being such blocking agents. However the term "blocking agent" broadly reads upon any substance which interferes with the interaction of the receptor with its ligand. Beyond the species of blocking agents disclosed instantly as soluble LT-β-R, anti-LT-β-R antibody and anti-LT ligand antibody, the instant specification does not provide descriptive support for the recitation of the genus "LT-β-R blocking agent."

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). It is respectfully submitted that the instant specification, in fact, clearly teaches only the possession of soluble LT-β-R, anti-LT-β-R antibody and anti-LT ligand antibody.

Accordingly, there is evidence that the full scope of the claimed invention was not in Applicant's possession as of the filing date sought.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

7. Claims 1, 3, 4, 15, 16, 19, 21, 22, 28, 29 and 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment methods using an LT-β-R blocking agent selected from soluble LT-β-R, anti-LT-β-R antibody and anti-LT ligand antibody, does not reasonably provide enablement for the full scope of "LT-β-R blocking agents." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to the use for treatment of agents which interfere with the normal signaling of the LT-β-R. The specification discloses antibodies which bind to LT-β-R or to its ligand and soluble LT-β-R. However, the term 'blocking agent' broadly reads upon any substance which would interfere with LT-β-R/lymphotoxin interaction. This would include compounds which have not been disclosed or yet discovered such as muteins, mimetics and small organic compounds, for example. The instant specification does not disclose any examples of such compounds and does not provide sufficient guidance to the artisan regarding the manufacture/isolation/use of such compounds. The artisan would not be able to reasonably predict the composition or structure of such a blocking agent and the discovery of such

undisclosed entities would require the exertion of a significant amount of inventive skill on the part of the practitioner.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

8. Claims 9, 13, 26 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The mAb BDA8 recited in claims 9, 26 and 34 and the mAb B9 recited in claim 13 are essential to the claimed invention. The reproduction of the exact same mAb is an extremely unpredictable event. The cell lines producing the mAbs must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the mAbs, and it is not apparent if the hybridomas are readily available to the public. If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridomas have been deposited under the Budapest Treaty and that the hybridomas will be **irrevocably** and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent**, whichever is longer. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be

made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from Applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the Applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

It is noted that the cell line producing the mAb BDA8 has been deposited with ATCC under the Budapest Treaty. Deposit information for the B9 antibody could not be found in the instant specification. Applicant should provide verified documentation of the deposits and amend the specification to indicate the B9 deposit information.

9. Claims 9, 13, 26 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

It is indefinite and ambiguous to recite the laboratory names "BDA8" [claims 9, 26 and 34] and "B9" [claim 13] to identify the monoclonal antibodies. The same designation, which appears to be the location of the well from which the original cell of the clonal line was isolated, is likely to be used by others as well to designate different cell lines. It is suggested that the corresponding accession or deposit number from the ATCC be recited in the claim.

Allowable Subject Matter

10. Claims 2, 5-8, 10-12, 14, 20, 23-25, 27 and 30-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

12. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
March 26, 2001

F. PIERRE VANDERVEGT
PATENT EXAMINER